UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

#18

SEP 17 1995

Francis J. Tinney
Patent Department
Warner-Lambert Company
2800 Plymouth Road
Ann Arbor, Michigan 48105

Re: Decision Granting Stay of Patent Term Extension Certificate for U.S. Patent No. 4,376,858

On September 5, 1995, a petition was filed by Warner-Lambert Company requesting that the Commissioner of the Patent and Trademark Office (PTO) suspend publication of a certificate of extension for U.S. Patent No. 4,376,858 until after a decision has been reached on a petition to the Food and Drug Administration (FDA), filed September 5, 1995, requesting reconsideration of the regulatory review period. Petitioner states that FDA's calculation of the regulatory review period for NEUTREXIN is incorrect. In the petition filed in the FDA petitioner argues that the dates relied upon in the calculation of the regulatory review period are incorrect.

The FDA published its determination of the relevant dates of the regulatory review period for NEUTREXIN in the August 30, 1994 Federal Register. 59 Fed. Reg. 44737 (1994). In this determination, the FDA recognized that the dates relied upon by Warner-Lambert were different from those used in their calculation of the regulatory review period and explained why different dates were used. The Federal Register notice also stated: "[a]nyone with knowledge that any of the dates as published is incorrect may, on or before October 31, 1994, submit to Dockets Management Branch . . . written comments and ask for redetermination." (emphasis added) In a letter dated March 22, 1995, the PTO was informed by the FDA that the determination of the regulatory review period was considered to be final.

However, the length the patent term extension is a function of the regulatory review period. Accordingly, if the FDA's calculation of the regulatory review period is incorrect, then the Patent and Trademark Office's calculation of the patent term extension will also be incorrect. The Patent and Trademark Office will not review the FDA's decision as to the relevant dates of the regulatory review period. Aktiebolaget Astra v. Lehman, Civil Action No. 93-1431-TFH (DC 1994) (PTO has no authority to change the FDA's determination of the regulatory review period) (copy attached). However, there is no need to immediately issue a certificate of extension and it would be proper to await FDA's decision on the petition for recalculation before issuing the patent term extension certificate.

In view of the above, the petition requesting a stay of issuance of a certificate of extension in U.S. Patent No. 4,376,858 is granted until a decision upon the petition for reconsideration is reached by FDA.

Gerald A. Dost

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Attachment: Copy of decision in Aktiebolaget Astra v. Lehman, Civil Action No. 93-1421-TFH (DC 1994) (unpublished)

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: NEUTREXIN

FDA Docket No.: 94E-0099

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AKTIEBOLAGET ASTRA,	
Plaintiff,	
v.	**Civil Action No. 93-1431-TFH**
BRUCE E. LEHMAN,	**Judge THOMAS F. HOGAN**
Assistant Secretary of Commerce and Commissioner of Patents and Trademarks,	
Defendant.	

ORDER

Upon consideration of COMMISSIONER'S MOTION FOR SUMMARY JUDGMENT and the opposition and reply, it is, for the reasons set forth in the Court's Memorandum Opinion hereby

ORDERED, that the Commissioner's motion be GRANTED; and it is further

ORDERED that Aktiebolaget Astra's CROSS-MOTION FOR SUMMARY JUDGMENT be DENIED; and it is further

ORDERED that this case is DISMISSED.

Date: March 10th, 1994

THOMAS F. HOGAN
U.S. District Judge

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(Rev. 8/82)

20

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AKTIEBOLAGET ASTRA,

Plaintiff,

v.

BRUCE E. LEHMAN,

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks,

Defendant.

Civil Action No. 93-1431-TFH

Judge THOMAS F. HOGAN

MEMORANDUM OPINION

This case is before the Court on the cross-motions for summary judgment of Defendant, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks ("Commissioner"), and Plaintiff Aktiebolaget Astra ("Astra"). For the reasons set forth below, the Court grants the Commissioner's Motion for Summary Judgment and denies Astra's Motion for Summary Judgment.

I. Background

(a) Statutory Framework

Section 156 of Title 35 of the United States Code provides for extension of the original term of a patent covering a product or the use of a product that has undergone certain premarketing regulatory reviews by the Department of Health and Human Services ("HHS") or the Department of Agriculture. 35 U.S.C. § 156. Section 156 provides that, subject to specified reductions and conditions, an eligible patent "shall be extended by a time equal to the regulatory review period." Id. § 156(c).

For a new drug, antibiotic drug or human biological product, the regulatory review period is the sum of a "testing phase" and an

19

"approval phase." The testing phase is defined as the period between the effective date of the product's exemption under subsection 505(i) of the Federal Food Drug, and Cosmetic Act, 21 U.S.C. § 355(i), and the filing of a new drug application with the FDA under section 505 of that Act. 35 U.S.C. § 156(g)(1)(B)(i). The "approval phase" is defined as the time between the filing of a new drug application with the Food and Drug Administration ("FDA") under section 506 of that Act and the approval of the drug for marketing under that section. Id. § 156(g)(1)(B)(ii). The extension period for the product used in the patent at issue in this case, however, includes only one-half of the "testing phase." Id. § 156(c)(2). Thus, the applicable period of extension is the sum of the approval phase and one-half of the testing phase.

(b) Regulatory Framework

The Commissioner, in its brief, describes the rather involved procedures for obtaining a patent term extension.[1] To obtain an extension,

> [t]he patent owner must file an application with the Commissioner. 35 U.S.C. § 156(d). The application must include, inter alia, (1) information sufficient for the Commissioner to determine eligibility for an extension and (2) information to enable the Commissioner and the Secretary of Health and Human Services to determine the length of the period of extension. Id. § 156(d)(1)(C). PTO's regulations require that the application set forth the relevant regulatory review dates. 37 C.F.R. § 1.740(a)(10)(i).
>
> Within 60 days after the filing of the application the Commissioner must submit a copy of the application to the Secretary of Health and Human Services. 35 U.S.C.

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[1] Astra does not challenge this account of the relevant procedures.

§ 156(d)(2)(A). Within 30 days of the receipt of the application, the Secretary must review the dates in the application and determine the applicable regulatory review period for the product. Id. § 156(d)(2)(A). The Secretary must inform the Commissioner of the determination and publish it in the Federal Register. Id.

The Secretary's responsibilities under 35 U.S.C. § 156 have been delegated to the FDA. 21 C.F.R. §§ 5.10(a)(27) and 5.27. FDA's regulations set forth the procedures which will be used in determining the regulatory review period. Id. §§ 60.20 - 60.26. Section 60.20 provides that FDA will consult its experts and records to verify the dates asserted in the application. Id. § 60.20(a). After the determination has been made, FDA informs PTO and the applicant and publishes the determination in the Federal Register. Id. §§ 60.20(b) and (c). The Federal Register notice will include not only the regulatory review period but the length of the testing and approval phases. Id. § 60.20(c)(7).

The FDA's regulations also provide that any person may request for revision of the regulatory review period determinations within 60 days of publication in the Federal Register. Id. § 60.24(a). If FDA revises its determination, it will notify the applicant and PTO and publish the revision in the Federal Register. Id. § 60.24(c). FDA's decision is considered final 180 days after publication of the notice in the Federal Register. Id. § 60.26(a).

Once notified by FDA of the length of the regulatory review period, including the length of the testing and approval phases, PTO makes a final determination of eligibility. If the patent is otherwise eligible, PTO must issue an extension for the period specified in 35 U.S.C. § 156(c). 35 U.S.C. § 156(e)(1). Under § 156(c), the period of extension is the regulatory review period subject to certain reductions. In determining the length of an extension, PTO uses the regulatory review period determined by FDA on behalf of the Secretary of HHS. 37 C.F.R. § 1.775(b). Deductions from the regulatory review period are made as provided in the statute. 35 U.S.C. § 156(c), 37 C.F.R. § 1.775(c).

The Commissioner informs the applicant of eligibility and the length of the extension by a notice mailed to the applicant. Id. § 1.750. The notice is the final determination as to eligibility and length of the extension. Id. Applicant is allowed a single request for reconsideration.

Id. The Commissioner then issues a certificate indicating the term of the extension. Id. § 1.780. Commissioner's Brief at 4-7.

(C) Factual Background

The parties agree that the material facts underlying this complaint are not in dispute.

Astra owns U.S. Patent No. 4,215,113 ("the '113 patent") issued July 29, 1980. The patent claims a method for combating viral infections using phosphonoformic acid, the active ingredient of the pharmaceutical FOSCAVIR. Astra Opposition at 4. An Investigational New Drug Application ("IND") for FOSCAVIR became effective on January 22, 1987, beginning the testing phase of the regulatory review period. On April 2, 1990, Astra maintains that it initiated the submission of its New Drug Application ("NDA") for FOSCAVIR. Id.[2] It states that on April 5, 1990, the FDA indicated that it had received Astra's April 2 submission and that it would initiate review. Astra claims that the FDA communicated with it by telephone regarding the NDA submission in the summer of 1990, and that it informed the FDA that the final submission of the NDA was planned for early September. On September 20, 1990, according to Astra, the FDA received this final submission. The FDA approved the NDA under 21 U.S.C. § 355 on September 27, 1991.

On November 26, 1991, Astra applied for an extension of the '113 patent. PTO forwarded a copy of the extension application to

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[2] Though the Commissioner does not consider Astra's communications with the FDA to be part of its administrative record, Astra's account of this correspondence is included for the sake of completeness.

the FDA by letter dated December 31, 1991. The letter asked for assistance in confirming that FOSCAVIR had been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) prior to commercial marketing and use. The letter also noted that preliminary review indicated that the subject matter appeared to be eligible for extension under section 156. Comm'n Exh. 1 at 139.

The FDA responded in a letter dated February 27, 1992. The letter states:

> A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required by 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the active ingredient, foscarnet sodium.
>
> The [NDA] was approved on September 27, 1991, which makes the submission of the patent term extension application on November 26, 1991, timely within the meaning of 35 U.S.C. [§] 156(d)(1).
>
> Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Comm'n Exh. 1 at 140.

PTO determined that the '113 patent was considered eligible for patent term extension and requested that the FDA determine the applicable regulatory review period by letter dated March 2, 1992. The letter stated that "a determination by [the FDA] of the regulatory review period is necessary." Comm'n Exh. 1 at 141.

The FDA determined that the total regulatory review period was 1,709 days. The testing phase was determined to be 1,337 days and

the approval phase 372 days. The FDA derived these periods from the following dates: January 22, 1987 (effective date of IND application filed with FDA); September 20, 1990 (Astra submits completed NDA to FDA); and September 27, 1991 (FDA approves NDA). The FDA published its determination of these dates in the April 13, 1992 Federal Register. 57 Fed. Reg. 12832 (1992). In this determination, the FDA recognized that Astra claimed an earlier date for the submission of the NDA, noting that Astra made submissions on April 2, April 25, September 18, and September 20, 1990. Id. at 12833. The Federal Register notice also stated:

> Anyone with knowledge that any of the dates as published is incorrect may, on or before June 12, 1992, submit to the Docket Management Branch . . . written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 13, 1992, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period.

Id. Astra did not request revision of the FDA's determination of the regulatory review period or the relevant dates under the FDA's regulations, and by letter dated October 22, 1992, the FDA informed the PTO that the FDA considered its regulatory review period determination to be final.[3]

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[3] Astra claims, however, that at no time did it "receive any direct communication from the FDA other than a copy of the letters to the USPTO. The FDA did not directly notify Astra of any time limit for review. . . ." Astra Opposition at 6. The Commissioner disputes Astra's suggestion that it did not receive actual notice of the FDA's determination at the time it was made. Commissioner's Response at 5. This dispute is not material, however, because Astra must be charged with constructive notice of the FDA's determination by virtue of its publication in the Federal Register. 44 U.S.C. § 1507; Federal Crop Ins. Corp. v. Merrill, 332 U.S. 380, 385 (1947).

The FDA, sua sponte, amended its regulatory review period determination to a total of 1,711 days, comprising a 1,338 day testing phase and a 373 day approval phase. 58 Fed. Reg. 6285 (1993).

PTO calculated the extension applicable to the '113 patent based solely on the regulatory review period determined by the FDA. It added the approval phase of 373 days to half the 1,338 day testing phase (i.e., 669 days) for a total extension of 1,042 days. PTO issued a Notice of Final Determination reflecting this calculation on February 10, 1993. Comm'n Exh. 1 at 150.

Astra requested reconsideration of the extension period, asserting that the FDA's determination of the approval phase was in error. It claimed that "[t]he FDA ignored, without proper basis, the earlier April 2, 1990 initial submission date when the applicant initially submitted the first section of the NDA application." Comm'n Exh. 1 at 153-54. Astra did not, however, assert that PTO had made a calculation error. The PTO denied Astra's request for reconsideration. Comm'n Exh. 1 at 157-58. On May 20, 1993, PTO issued a Certificate Extending Patent Term for 1,042 days. Comm'n Exh. 1 at 161. This complaint followed

II. Analysis

This action arises under the United States Constitution, 35 U.S.C. § 156, and the Administrative Procedures Act, 5 U.S.C. §§ 551-706. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

The Court may grant summary judgment if there are no genuine issues as to any material facts and the moving party is entitled to a judgment as a matter of law. Fed. R. Civ. P. 56(c). In this case the parties agree that the relevant facts are beyond reasonable dispute. The only question to be decided is whether the Commissioner or Astra is entitled to a judgment as a matter of law.

The parties agree that the dispositive issue in this case is whether the PTO erred in limiting the extension of the term of the '133 patent to 1,042 days. They further agree that the following sub-issue is dispositive of that more general dispute: Does the PTO have authority under 35 U.S.C. § 156 to review and set aside a final determination of a regulatory review period under provisions of 35 U.S.C. § 156(c) made by a delegate of the Secretary of Health and Human Services, namely, the FDA?

When reviewing an agency's construction of a statute it administers, if a court determines that Congress has directly spoken on the precise question at issue, the court's job is at an end. It must enforce the clearly expressed intent of Congress. Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842 (1984). In this case the statute is plain. Although 35 U.S.C. § 156(d)(1)(C) provides that the Commissioner and the Secretary of HHS are jointly to determine the extension period, § 156(d)(2)(A) explicitly provides that one component of this determination, the length of the regulatory review period, shall be calculated by the Secretary. After a copy of the extension application is forwarded by PTO to the appropriate Secretary, "the

Secretary receiving the application shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period." 35 U.S.C. § 156(d)(2)(A) (emphasis added). The statute thus plainly mandates that the Secretary, not the PTO, must calculate the regulatory review period. This mandate is embodied in the PTO's regulations providing that "[t]he length of the regulatory review period for a human drug, antibiotic drug or human biological product will be determined by the Secretary of Health and Human Services. 37 C.F.R. § 1.775(c).[4] This unambiguous statutory language prevails in the absence of clearly expressed legislative intent to the contrary. Hoechst Aktiengesellschaft v. Quigg, 917 F.2d 522, 526 (Fed. Cir. 1990). The Court finds no expression of contrary intent in either the statute's structure or legislative history.

To support its claim that both the Secretary and the Commissioner are charged with determining the applicable review period, Astra points to the fact that § 156(d)(1)(C) requires that an applicant supply such information as is necessary "to enable the Commissioner and the Secretary of Health and Human Services . . . to determine the period of extension under subsection (g). . . ." 35 U.S.C. § 156(d)(1)(c) (emphasis added). Section 156(g), in turn, primarily defines the term "regulatory review period." Id. § 156(g). Astra asserts: "Congress clearly intended that the USPTO

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[4] Because the Court determines that the statutory language is unambiguous, it necessarily holds that Astra has put forward no argument to suggest that the PTO's interpretation of 35 U.S.C. § 156 as embodied in 37 C.F.R. § 1.775(c) is not "permissible" within the meaning of Chevron, 467 U.S. at 843.

would perform more than the ministerial act of calculating the extension by halving the testing period and adding the approval period provided by the [Secretary.]" Astra Opposition at 12. The Court is unpersuaded.

Despite the cross-reference between § 156(d)(1)(C) and § 156(g), Congress does not appear to have used the terms "period of extension" and "review period" interchangeably. Section 156(g) uses each term to denote a different determination and clearly defines a role for the PTO in determining the extension period, as opposed to the regulatory review period. See, e.g., id. § 156(g) (limiting to five years "the period of extension determined on the basis of the regulatory review period" when patent was issued after enactment of § 156 (emphasis added)). The Court may not expand the specific, if narrow, role of the PTO prescribed by Congress.

Astra also contends that nothing in § 156(d)(2)(A) states or implies that the Secretary's "initial" determination of the regulatory review period is unreviewable by the Commissioner. Opposition at 13. Contrary to Astra's assertions, however, nothing in the statute suggests that this determination is an "initial" or "interim" determination. Concededly, as a purely logical matter, the Congressional command that the Secretary shall determine the regulatory review period does not preclude the PTO from independently making such a determination. The suggestion, however, that Congress intended the statute to permit competing determinations of the regulatory review period is unsupportable. The weakness of Astra's position is demonstrated by the fact that

Congress has, for instance, provided that the Secretary's allegedly "interim" determination be published in the Federal Register for public scrutiny, 35 U.S.C. § 156(d)(2)(A), while any hypothetical and unmentioned "review" of this determination by the Commissioner — that could potentially eviscerate the "interim" determination — is completely free from this same requirement. It is apparent that Congress has not generated the anomalous structure Astra attributes to it. Rather, it has fashioned a meticulous statute that governs the coordinated decisionmaking of two federal agencies. Astra's imagined avenues of review have no place in this carefully detailed scheme. There is no conflict between the statute's structure and its language.

The most credible basis for its argument that Astra has put forward is a single passage of the House Report discussing section 156(e). It states:

> The Commissioner would make the final determination that a patent is eligible for extension under § 156(a), that the requirements of § 156(d) have been met, and that the period of extension will be the period prescribed in § 156(d). Once these findings are made, the Commissioner would be required to issue a certificate of extension to the applicant.

H.R. Rep. No. 98-857, Part I, 98th Cong., 2d Sess. 42, reprinted in 1984 U.S.C.C.A.N. 2647, 2675 (emphasis added). This passage perhaps suggests a greater degree of activity on the part of the Commissioner than does the statute standing alone. Astra's argument is undermined, however, by at least one other portion of the legislative history. This same House Report includes a letter from the Director of the Congressional Budget Office which states:

> The activities described in Title II of this bill [the Drug Price Competition and Patent Term Restoration Act] would be performed by both the FDA and the PTO. FDA would be responsible for determining the applicable regulatory review period for a product used in setting the length of the patent extension. FDA would also monitor diligence in product testing which must be shown in order for a manufacturer to receive the maximum possible patent extension. . . . PTO would be responsible for handling patent extension eligibility.

H. Rep. No. 98-857, Part II, 98th Cong., 2d Sess. 33, reprinted in 1984 U.S.C.C.A.N. 2716-17 (emphasis added). This passage clearly supports the interpretation put forward by the Commissioner. Even assuming that the legislative history cited by Astra is more authoritative than that cited by the Commissioner, Astra has at most demonstrated a possible dissonance between Congress's thought and its expression. This dissonance, however, can scarcely be exaggerated into a conflict between the statute's plain language and its legislative history. The Court is not free to ignore the statute's express terms.

III. Conclusion

For the foregoing reasons, the Court holds that the determination of the regulatory review period is committed by statute to the Secretary of Health and Human Services and PTO is not authorized to redetermine or set aside the period determined by the Secretary. It cannot be said that the decision denying Astra's request for reconsideration was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A). The Commissioner's Motion for Summary Judgment is, accordingly granted.

As to Astra's Motion for Summary Judgment, the Court's holding that the Commissioner properly applied 35 U.S.C. § 156 necessarily entails that it cannot grant summary judgment in Astra's favor. Accordingly, Astra's motion is denied.

Date: March 10th, 1994

THOMAS F. HOGAN
U.S. District Judge